DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: DEC 22 2003

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: *Guatteria gaumeri* (Yumel)

Notifier: Mark Weiner
668 North Coast Highway # 253
Laguna Beach, CA 92651

Date Received by FDA: March 19, 2003

90-Day Date: June 17, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Vickey Lutwak for
Gloria Chang

P drive/ NDI/ NDI File Closeout/DDSP SOP closeout process...

95S-0316

RPT184

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, Maryland 20740

MAY 23 2003

Mr. Mark Weiner
668 North Coast Highway #253
Laguna Beach, California 92651

Dear Mr. Weiner:

This is to inform you that the notification, dated March 12, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on March 19, 2003. Your notification concerns the substance you identified as yumel. You state that the Latin binomial name of the substance is *Guatteria Gaumeri* and your product contains 1 part yumel and 5 parts of alcohol. Your notification states the suggested condition of use is 6 to 10 drops before meals.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification on a new dietary ingredient. The notification you sent us concerning yumel does not comply with the requirements of 21 CFR 190.6 and is incomplete. For example, the Latin binomial name of your product does not meet the requirements at 21 CFR 190.6(b)(2) which states that it should include the name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical. You did not provide a description of your product as required by 21 CFR 190.6(b)(3) and provide adequate information on the serving level and total daily maximum serving level and other conditions of use.

Therefore, you have not met the requirement to notify the FDA of the basis upon which you have concluded that a dietary supplement containing your product is reasonably expected to be safe as required by 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Accordingly, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains new dietary ingredient(s) for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

In addition, in any resubmission, we would encourage you to clearly describe how the characteristics of any test materials submitted in support of safety are quantitatively and qualitatively related to the dietary supplement to be marketed.

Your notification will be kept confidential for 90 days after the filing date of March 19, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

March 12, 2003

From:
Mark Weiner
668 North Coast Highway #253
Laguna Beach, CA 92651

Attention:
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington D.C., 20204

To Whom It May Concern:

The name of the new dietary ingredient is yumel. The Latin binomial name is Guatteria Gaumeri. Yumel is a common tree found in Mexico, whose extracts are used by people in many regions throughout Mexico. The new dietary supplement will be made up of 1 part yumel and 5 parts alcohol. Thousands of people in Mexico have used yumel as a dietary supplement for the past 50 years, experiencing absolutely no side effects whatsoever. It is recommended that yumel be taken 6 to 10 drops before meals. We are bringing yumel to market under the Dietary Supplement Health and Education Act of 1994.

The attached material is evidence supporting the safety of yumel. If you have any questions, please contact Jasun Weiner. He can be reached at (949) 233-7761.

Sincerely,

Mark Weiner

83802

Institute for Alternative Medicine

Oriental Medicine • Natural Therapeutics

March 6, 2003

To Whom It May Concern:

I have been using mother tincture of yumel in my practice since the early 1970's. I was introduced to yumel while attending postgraduate programs at the Free School of Homeopathic Medicine, Mexico City DF in 1973 and at the National School of Homeopathic Medicine, National Polytechnic Institute Mexico City DF in 1974.

I have probably worked with from three to five patients per year who I had using yumel as a dietary supplement. In all my time working with yumel, I have never had a patient experience negative side affects.

Dr. Robert J. Broadwell

18837 Brookhurst Street, Suite 210 • Fountain Valley, CA 92708 • (714) 965-9266 • Fax (714) 965-9268

Propulsora de Homeopatía, S.A.
LABORATORIOS
FUNDADOR DR. RAFAEL LOPEZ HINOJOSA.

MIRTO 26 Y 28 MEXICO, D. F. 06400
TELS. (5)547-9483 (5)547-5735
FAX (5)547-8279 (5)547-3707
e-mail: similia@similia.com.mx
www.similia.com.mx

March 8, 2003

To Whom It May Concern:

We have been processing and distributing yumel for the last 50 years. We sell yumel to homeopathic and natural food stores throughout Mexico. We have never had a report of any problems, physical or otherwise, resulting from the use of yumel. Yumel can be taken on a full or empty stomach without affecting the body in any negative way. Yumel can be taken over a long period of time and will not provoke any negative effects whatsoever. For the preceding reasons, we attest that yumel provides no threat to the safety of the people who use it.

Sincerely,

M. C. Maritza del Carmen Cázarez Ríos
Quality Control Manager
Propulsora de Homeopatía

65 años

March 3, 2003

Mark Weiner's Testimonial of Yumel:

I have been using yumel as a dietary supplement. I have experienced nothing but positive results from its use. I take approximately 10 drops of yumel before I eat a meal. I normally take yumel 2 to 3 times every day. I have never experienced side effects. I have found yumel to be totally safe.

Sincerely,

Mark Weiner